IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION
CIVIL ACTION NO.: 5:03CV95

CHARLES DELLINGER,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**MEMORANDUM AND ORDER**
	)	
PFIZER INC and PARKE-DAVIS, a division of Warner-Lambert Company,	)	
	)	
Defendants.	)	
	)	

THIS MATTER is before the Court on the following motions and memoranda: (1) Defendants' Motion for Summary Judgment and Memorandum in Support, both filed November 30, 2005 (Documents ##48, 49); (2) Plaintiff's Response in Opposition, filed January 27, 2006 (Document #53); (3) Defendants' Reply, filed February 10, 2006 (Document #54); and (4) Defendants' Motion to Exclude Testimony by Christopher Keeys and Memorandum in Support, both filed February 14, 2006. (Documents ##55, 56.)

Having carefully considered the arguments, the record, and the applicable authority, for the reasons stated herein the Court will *grant* Defendants' Motion for Summary Judgment and Defendants' Motion to Exclude Testimony by Christopher Keeys.

I. FACTUAL AND PROCEDURAL HISTORY

For the purposes of this motion, the Court accepts the following facts as derived from the Plaintiff's Complaint as true. *See Anderson v. Liberty Lobby*, 477 U.S. 242, 255 (1986) (when considering a motion for summary judgment, the court must view the facts and inferences in the light

most favorable to the party opposing the motion).

In December 1994, Plaintiff Charles Dellinger ("Plaintiff") underwent surgery for a lower back injury in Gastonia, North Carolina. (Compl. ¶ 7.) After experiencing continuous back trouble and associated pain, Plaintiff underwent a second surgery in September 1996 at Frye Regional Medical Center in Hickory, North Carolina. (Miller Dep. at 6.) Following the September 1996[1] back surgery, Plaintiff complained to his physician, Dr. Peter Miller, that he was experiencing extreme pain. (Compl. ¶ 8.) As a result, Dr. Miller told the Plaintiff about a new drug for pain management which had come highly recommended. (*Id*.) Dr. Miller had learned about Neurontin through various articles and through the experience of other physicians.[2] (Miller Dep. at 50.) On September 19, 1996, Dr. Miller prescribed Neurontin for the Plaintiff's acute and chronic back pain. (Dellinger Dep. at 49-50.) The prescription for Neurontin was for an "off-label" use, which refers to the use of a prescription drug for purposes other than those approved by the United States Food and Drug Administration ("FDA").[3] (Miller Dep. at 44; Compl. ¶ 5(g).)

Plaintiff took Neurontin from September 1996 through May 1997, at which point Dr. Miller took him off Neurontin because the medicine did not appear to be helping Plaintiff's pain.[4] (Miller Dep. at 15; Dellinger Dep. at 18, 28.) Dr. Miller tried to manage the pain by increasing Plaintiff's

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[1] Plaintiff's Complaint identified date of second surgery as September 1997. However, through course of depositions and discovery, the second surgery actually occurred in September 1996. (Miller Dep. at 6; Dellinger Dep. at 15.)

[2] On August 12, 2004, Plaintiff and Dr. Miller had a meeting in which Dr. Miller stated that he learned about Neurontin by reading articles. (Dellinger Dep. at 50.)

[3] In December 1993, the FDA approved Neurontin (gabapentin) as adjunctive therapy for the sole treatment of certain types of seizures in adult patients suffering from epilepsy. (Compl. ¶ 5(b).)

[4] On May 29, 1997, Plaintiff was doing poorly due to stress, lack of sleep, depression and continuous pain. (Miller Dep. at 14-15.)

dosage of another prescription drug, doxepin. (Miller Dep. at 16.) However, Plaintiff's leg pain worsened after he stopped taking Neurontin. (*Id.* at 17.) Consequently, on July 31, 1997, Dr. Miller discontinued the doxepin and re-prescribed Neurontin. On August 27, 1997, Dr. Miller prescribed Duract because Plaintiff was still experiencing significant pain. (Miller Dep. at 17.) In late November, Dr. Miller discontinued the Duract due to negative side effects[5] and prescribed Prozac for Plaintiff's depression. (*Id*. at 18-19.)

In early 1998, Plaintiff began to experience severe lethargy, weakness, malaise, nausea and a metallic taste in his mouth. (Compl. ¶ 9.) On March 18, 1998, Plaintiff developed a fever and went to the emergency room at Frye Regional Medical Center in Hickory, North Carolina, where he was diagnosed with pneumonia.[6] (*Id*.) At the time of admission, Plaintiff was taking Neurontin, Prozac, Soma, Vicodin, and Elavil. (Exhibit G at 2.) Plaintiff was taken off *all* medications during his hospital stay. (Miller Dep. at 26-27.)

On March 19, 1998, Plaintiff collapsed and was placed in the Intensive Care Unit (hereinafter "ICU"). (Compl. ¶ 9.) On March 20, 1998 Plaintiff was placed on a ventilator and remained on life support until April 5, 1998. (*Id*.) While the Plaintiff was in ICU, his wife was approached by Dr. Matt Brown at Frye Regional Medical Center who advised her that she should question the use of Neurontin by her husband and research the drug. (V. Dellinger at 28.) At this point, Plaintiff's wife became concerned with Neurontin. (Compl. ¶ 10.) While the Plaintiff remained in the hospital, Plaintiff's wife contacted Dr. Miller and expressed her concerns. (V. Dellinger Dep. at 31.)

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[5] Plaintiff discontinued Duract because it caused bouts of diarrhea. (Miller Dep. at 18.)

[6] Medical records are unclear as to whether Plaintiff had pancreatitis. (Miller Dep. At 28-29; Discharge Summary of Dr. Thomas Ray, Exhibit H.)

Plaintiff's wife did not want Plaintiff to resume taking the Neurontin.[7] (*Id.*)

On April 7, 1998, Plaintiff began to improve and was removed from ICU. (V. Dellinger Dep. at 31.) Plaintiff remained in the hospital until April 23, 1998, where he was discharged to a rehabilitation facility. (*Id.*). Plaintiff remained in the rehabilitation facility until April 28, 1998. (Compl. ¶ 11.) After his discharge from the facility, Plaintiff refused to continue the use of Neurontin. (*Id.*) Gradually, Plaintiff's health improved. After hospitalization, Plaintiff continued to take prior medication such as Vicodin, Prozac and Elavil. (Miller Dep. at 20,24.) It took Plaintiff over a year to be able to feed, bathe and care for himself. (Compl. ¶ 11.)

In the winter of 2003, while searching the Internet for research studies involving Neurontin, Plaintiff's wife learned of the case, Congress of California Seniors, et al. v. Pfizer, Inc. and Parke-Davis. (Compl. ¶ 6.) After researching the case and other related cases, Plaintiff and his wife learned that Pfizer, Inc., and Parke-Davis (hereinafter "Defendants") had developed a well-designed and extensive scheme to promote Neurontin as an "off-label" drug. (Compl. ¶ 3.) Reportedly, the scheme involved Defendants' violations of statutes and regulations that prohibit a manufacturer of prescription drugs regulated by the FDA from promoting or marketing the use of the drugs for purposes or in dosages other than those approved by the FDA. (*Id.*) Promotion of "off-label" uses of prescription drugs, such as Neurontin, is strictly illegal and contrary to policies and regulations of the United States Government. (*Id.*)

More specifically, in order to increase the sale of Neurontin, Defendants developed a strategy to take advantage of a loophole in the law regarding "off-label" promotions by hiring "medical

[7] Dr. Miller does not remember the Plaintiff's wife speaking with him about Neurontin, nor does he have a record of the conversation taking place. (Miller Dep. at 27.)

liaisons." (Compl. ¶ 5(i)(j).) Allegedly, "medical liaisons" were trained to use knowingly false information about Neurontin's "off label" uses when speaking with doctors and were told to lie about their credentials. (*Id.*) "Medical liaisons" also allegedly engaged in repetitive distribution of non-scientific, anecdotal data designed to convince physicians that "off-label" uses of Neurontin were safe and effective. (Compl. ¶ 5(i).) According to the Plaintiff, the key to selling Neurontin as an "off- label" drug was misrepresentation in that the fraudulent promotional scheme by Parke-Davis corrupted the information process relied upon by doctors in their medical decisions. (Compl. ¶ 5(n).) Plaintiff further contends that no valid scientific evidence supports the contention that Neurontin is safe and effective for pain or other "off-label" uses.[8] (Compl. ¶ 5).) In fact, Parke-Davis is currently conducting actual legitimate trials investigating the use of Neurontin for relief of certain types of pain. However, these trials are not complete.[9] (*Id.*)

As a result of the illegal promotional scheme, Defendants' parent company, Warner-Lambert, and the Government entered into a global criminal and civil settlement agreement in the United States District Court of Massachusetts. Govmt's Sentencing Mem., *U.S. v. Warner-Lambert, LLC*, Criminal No. 04-10150 RGS. Warner-Lambert plead guilty to the introduction of a misbranded drug into interstate commerce and the introduction of an unapproved new drug into interstate commerce, in violation of 21 U.S.C. §§ 331(a), 331(d), 352(f)(1) and 355(a). *Id.*

Plaintiff asserts the illegal promotion of Neurontin as an "off-label" drug resulted in Plaintiff's illness and subsequent hospitalization. (Compl. ¶ 3.) On June 23, 2003, Plaintiff filed a

[8] However, Plaintiff concedes that no medical or scientific literature states that Neurontin is capable of causing illnesses such as pneumonia or pancreatitis. (Keeys Dep. at 37.)

[9] If a manufacturer wishes to market or promote a drug for new uses, it must demonstrate with adequate studies, to the FDA's satisfaction, that the drug is safe and effective for the new uses. *See* 21 C.F.R. § 314.54.

complaint alleging that Defendants' actions gave rise to the following causes of action: breach of implied warranty, breach of express warranty, fraud, violation of North Carolina's unfair and deceptive trade practices act, and a statutory product liability action under Chapter 99B of the North Carolina General Statutes. Plaintiff's unfair and deceptive trade practices claim under N.C. Gen. Stat. § 75-1.1 is the only cause of action that survived Defendants' motions to dismiss pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6). (Document #28.) Plaintiff seeks treble damages, attorneys' fees and costs. (Compl. ¶ 25.)

II. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 56(b), a party against whom a claim is put forward may, at any time, move for a summary judgment in that party's favor. FED. R. CIV. P. 56(b). A summary judgment should be granted "if the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); *Charbonnages de France v. Smith*, 597 F.2d 406 (4th Cir. 1979). The movant bears the initial burden of informing the court of the grounds for its motion and demonstrating the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine issue exists if the evidence is able to show that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 248.

However, the party opposing the summary judgment may not rely upon mere allegations or denials, and a "mere scintilla of evidence" is inadequate to overcome summary judgment. *Id*. at 249-50. The fact or facts in question must be material, thereby affecting the outcome of the case. *Id*. at 252. Furthermore, when ruling on summary judgment motions, courts must view the facts and all

reasonable inferences in the light most favorable to the non-moving party. *Id*. at 255; *Evans v. Techs. Applications & Serv. Co.*, 80 F.3d 954, 958 (4th Cir.1996).

III. DISCUSSION OF CLAIMS

A. Plaintiff Alleges Facts That, If Proven, Fall Within The Scope Of N.C. Gen. Stat. § 75-1.1

In order to bring a claim under North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA"), a plaintiff must prove the following: "(1) an unfair or deceptive act or practice, or an unfair method of competition, (2) in or affecting commerce, (3) which proximately caused actual injury to the plaintiff or to his business." *Brinkman v. Barrett Kays & Assocs., P.A.*, 155 N.C. App. 738, 743, 575 S.E.2d 40, 44 (2003).

Defendants do not contend that Plaintiff failed to prove the first two elements of an unfair and deceptive trade practices violation. Instead, Defendants contend the Court should dismiss Plaintiff's claim of unfair and deceptive trade practices on the grounds that the statute does not provide redress for consumers' personal injury damages. (Defs.' Mem. in Supp. of Mot. for Summ. J. p. 10.) In response, Plaintiff contends that an action for unfair and deceptive practices is its own separate and discrete statutory action and is, therefore, *sui generis*. (Pl.'s Mem. in Opp'n p. 7.)

As an initial matter, the Court is not convinced that Plaintiff has no "economic injury." Defendants posit that Plaintiff has "no out-of-pocket loss relating to the cost of the drug or any other consumer injury." (Defs.' Mem. in Supp. of Mot. for Summ. J. at 10.) Defendants' argument relies in part on the fact that Plaintiff received worker's compensation benefits and was not required to pay for the Neurontin at the time it was prescribed or any of the costs associated with his illness. (Defs.' Mem. in Supp. of Mot. for Summ. J. at 10, 12.) However, in evaluating whether Plaintiff's action

is cognizable (as opposed to the calculation of a monetary damages award), the Court considers the *existence* of Plaintiff's damages (i.e., medical expenses, lost wages, and the like) – not whether Plaintiff's damages were offset by a collateral source.

Secondly, N.C. Gen. Stat. § 75-16 fails to include or exclude specific types of injuries giving rise to a cause of action under the statute. Section 75-16 provides a cause of action:

> "[i]f *any person shall be injured* or the business of any person, firm or corporation shall be broken up, destroyed *or injured by reason of any act or thing done by any other person*, firm or corporation in violation of the provisions of this Chapter..."

N.C. GEN. STAT. § 75-16 (2006) (emphasis added). Thus, the provision expressly contemplates persons being injured and that a cognizable injury may be the result "of any act or thing done by any other person. . . " *Id.* Section 75-16 does not support Defendants' position.

Notwithstanding the statute, Defendants argue that "the UDTPA nowhere provides for the recovery of damages resulting from a claim of personal injury," due to the Act's treble damages provision and the lack of case law addressing personal injuries under the Act. (Defs.' Mem. in Supp. of Mot. for Summ. J. at 10-11.) Defendants point to the availability of treble damages under the UDTPA as *evidence* that recovery under the Act is limited to economic damages incurred by consumers as opposed to damages resulting from personal injury. On the contrary, Defendants' argument essentially advances a suggested policy. Further, Defendants concede that the private enforcement aspect of the UDTPA is necessary to protect "aggrieved consumers" given that "common law remedies were often ineffective." *Marshall v. Miller*, 302 N.C. 539, 543, 276 S.E.2d 397 (N.C. 1981). Here, Plaintiff's breach of warranty and product liability claims were time-barred by the time Plaintiff discovered the alleged fraudulent scheme and are, therefore, ineffective

remedies. (*See* July 7, 2004 Order) According to North Carolina case law, such gaps in the consumer protection laws are precisely what the UDTPA contemplated. *Id.*; *Bernard v. Cent. Carolina Truck Sales, Inc.*, 68 N.C. App. 228, 232, 314 S.E.2d 582 (N.C. App. 1984).

Additionally, Defendants' reliance on *Belcher v. Fleetwood Enters., Inc.*, is misplaced. (*See* Defs.' Mem. in Supp. of Mot. for Summ. J. p.10-11.) It is true that the plaintiffs in *Belcher* were unable to prove actual injury in support of their unfair and deceptive trade practices claim. *Belcher v. Fleetwood Enters., Inc.*, 162 N.C. App. 80, 85, 590 S.E.2d 15, 18-19 (2004) (summary judgment granted, given owner's prior statements that he had not suffered actual injury). However, the court interpreted actual injury in broad terms, contemplating that both personal injury damages and property damages might have been sought by the plaintiffs. *Belcher*, 162 N.C. App. at 82. Specifically, actual injury was defined as including: "the loss of the use of specific and unique property, the loss of any appreciated value of property, and such *other elements of damages as may be shown by the evidence.*" *Belcher*, 162 N.C. App. at 85 (emphasis added). Therefore, *Belcher* does not preclude personal injury damages.

Given the broad language of the statute, and the absence of legislative intent or case law to the contrary, there is no reason to exclude a consumer's personal injury from the category of injuries cognizable under the statute.[10] This Court declines to construe the Act as narrowly as suggested by Defendants.

[10] Other state statutes are construed more narrowly due to specific language and/or legislative intent provided for in the annotations. OR. REV. STAT. ANN. § 646.638 (West 2006); HAW. REV. STAT. ANN. § 480-13 (2006). However, in North Carolina, the statute provisions are not specific and allow for a more broad interpretation of injury. N.C. GEN. STAT. § 75-16 (2006).

B. Plaintiff's Claim Is Not Barred By The Three-Year Statute Of Limitations Applicable To Personal Injury Claims

A claim for unfair and deceptive trade practices pursuant to Chapter 75 of the North Carolina General Statutes is subject to a four-year statute of limitations.[11] N.C. GEN. STAT. § 75-16.2 (2006). According to Defendants, however, Plaintiff seeks to bring a "garden-variety" personal injury claim under the pretext of a consumer protection claim and should therefore be subject to the three-year statute of limitations applicable in personal injury cases. (Defs.' Mem. in Supp. of Mot. for Summ. J. p. 13.) Defendants' argument is without merit in that it is another attempt to re-characterize Plaintiff's action as one lying solely in tort.[12]

In support of this position, Defendants point to other state law causes of action that apply the three-year statute of limitations where personal injury is an essential element of the claim. For instance, North Carolina extends personal injury as an essential element in breach of express and implied warranty cases, thereby triggering a three-year statute of limitations. *See Humble v. Sara Lee Corp.*,168 N.C.App. 595, 608 S.E.2d 416 (2005) (unpublished); *Bernick v. Jurden*, 306 N.C. 435, 444-45, 293 S.E.2d 405, 411-12 (1982) (unpublished). However, North Carolina courts do not apply the same rationale in the context of an unfair and deceptive trade practices claim. *See Page v. Lexington Ins., Co.*, 628 S.E.2d 427 (N.C. Ct. App. 2006); *Belcher*, 162 N.C. App. 80, 590 S.E.2d 15 (2004); *Mitchell v. Linville*, 148 N.C. App. 71; 557 S.E.2d 620 (2001); *First Atl. Mgmt. Corp*. v. *Dunlea Realty Co.*, 131 N.C. App. 242, 507 S.E.2d 56 (1998). Indeed, North Carolina "has

[11] Defendants do not contend that Plaintiff's action is untimely if a four year statute of limitation applies. (Defs.' Mem. in Supp. of Mot. for Summ. J. p. 13-14.)

[12] Plaintiff's allegations are more broad than a mere personal injury claim in that the existence of criminal/civil proceedings in other forums, and the obvious societal harms that accompany such a scheme, distinguish the facts in this case from a garden-variety personal injury claim.

consistently treated UDTP claims as separate and distinct from other claims with respect to statutes of limitations." *Page*, 628 S.E. 2d at 430 (internal citation omitted). Plaintiff's unfair and deceptive trade practices claim is subject to the four-year statute of limitations expressly provided for within the Act.

C. Learned Intermediary Doctrine

Defendants contend Plaintiff's claim is barred by the learned intermediary doctrine, which states that a manufacturer or seller of a prescription drug has no legal duty to warn a patient of the dangerous tendencies of its drug, as long as sufficient warnings are provided to the prescribing physician. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984)*; Foyle v. Lederle Labs.*, 674 F. Supp. 530 (E.D.N.C. 1987). Defendants assert that even if Neurontin caused Plaintiff's injuries, it was ultimately up to the prescribing physician, Dr. Miller, to inform Plaintiff of Neurontin's dangerous propensities. (Defs.' Mem. in Supp. of Mot. for Summ. J. p. 24.)

Section 99B of the North Carolina General Statutes states: "no manufacturer or seller of a product shall be held liable in any *product liability* action for a claim based upon inadequate warning or instruction *unless* the claimant proves that the manufacturer or seller acted *unreasonably* in failing to provide such warning or instruction..." N.C. GEN. STAT. § 99B-5 (2006) (emphasis added). This provision applies solely to product liability actions rather than unfair and deceptive trade practices actions. Nonetheless, it bears noting that, even if the statute applied to unfair and deceptive trade practices claims, the illegal and fraudulent promotion of Neurontin as an "off-label" drug by the Defendants would appear to preclude Defendants' reliance on the learned intermediary doctrine. (Compl. ¶ 3.) By partaking in an illegal promotional scheme, Defendants failed to *reasonably* warn physicians, including Plaintiff's prescribing physician, Dr. Miller, about the dangerous propensities

of Neurontin as an "off-label" drug. (Compl. ¶ 5(n).) Therefore, the learned intermediary doctrine does not bar the Plaintiff's claim.

D. Plaintiff Fails To Present Relevant & Reliable Evidence Of Causation

An essential element to an unfair and deceptive trade practices violation is whether a defendant "proximately caused actual injury to the plaintiff." *Brinkman*, 155 N.C. App. at 743. Defendants contend Plaintiff's claim fails because there is no genuine issue of material fact as to whether Defendants' conduct or product caused Plaintiff's injuries. (Defs.' Mem. in Supp. of Mot. for Summ. J. p. 14.) More specifically, Defendants assert Plaintiff failed to establish general or specific causation through expert testimony. (*Id*. at 18.)

In order to survive Defendants' motion for summary judgment, Plaintiff must present evidence from which a reasonable juror could find (1) that Defendants' actions proximately caused Dr. Miller to prescribe Neurontin to the Plaintiff for an "off- label" use; and (2) that the use of Neurontin was a proximate cause of the Plaintiff's illness.

1. A Genuine Issue Of Fact Exists Regarding Whether Defendants' Alleged Unfair & Deceptive Trade Practices Proximately Caused Dr. Miller To Prescribe Neurontin

Defendants' role in promoting Neurontin as an "off-label" drug for pain management, and how Defendants' alleged unfair and deceptive trade practices affected Dr. Miller, if at all, gives rise to an issue of fact. Plaintiff alleges in his Complaint that based on misrepresentations made by the Defendants' "medical liaisons," physicians around the world were inclined to believe Neurontin could be safely prescribed for "off-label" usage. (Compl. ¶ 3.) In fact, Dr. Miller, along with others, prescribed Neurontin for "off-label" uses such as pain management. (Miller Dep. at 8-9.) Based on the Defendants' alleged illegal scheme to promote Neurontin as an "off-label" drug, circumstantial

evidence exists from which a reasonable juror could infer that Defendants' alleged actions influenced the medical community as a whole, with respect to the safe and effective uses for Neurontin.[13]

As for whether Defendants' actions wielded any influence over Dr. Miller, there is little evidence supporting Plaintiff's theory of the case. Dr. Miller testified he was initially inclined to prescribe Neurontin for an "off-label" use based on the experiences of other physicians and various medical articles.[14] (Miller Dep. at 50.) Dr. Miller also testified that he had observed positive results with previous patients. (Miller Dep. at 8-9.) Significantly, Dr. Miller's confirmed practice was to *not* speak with representatives of the drug companies. (Miller Dep. at 35.) Dr. Miller testified that this practice of not speaking with drug reps was adhered to by him personally as well as by his office staff. (*Id.*) In fact, Dr. Miller reported no other direct or indirect communications with Defendants. (Miller Dep. at 42-44.)

However, viewing the evidence in the light most favorable to Plaintiff, Dr. Miller could have been influenced by the professional opinion of one or more of his colleagues, who had been influenced by Defendants' alleged unfair and deceptive trade practices. Notably, Dr. Miller admits that sources are fairly limited concerning drug studies and findings. (Miller Dep. at 51-52.) In fact, Dr. Miller also concedes that his colleagues would have likely learned about the "off-label" usage of drugs through some study or report. (*Id.*) Therefore, based on the extensive misrepresentations made regarding scientific information of the "off-label" usage of Neurontin, there is a genuine issue

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[13] Defendants question the weight Plaintiff attributes to the related criminal proceedings given the fact that the offenses were strict liability offenses, and the relevant conduct admitted to for the purposes of the plea consisted of specific, non-fraudulent instances of conduct occurring in 1995 and 1996. (Defs.' Mem. in Supp. of Summ. J. at 16, n. 14.)

[14] While not determinative, Dr. Miller could not identify or recall any particular conversations with colleagues, or any studies or articles he relied upon in reaching his medical opinion that Neurontin could be safely prescribed to Plaintiff. (Miller Dep. at 33, 35 ,50-52.)

as to whether the Defendants' conduct indirectly caused Dr. Miller to prescribe Neurontin for an "off-label" use. Nevertheless, because Plaintiff fails to satisfy his burden of demonstrating a causal link between his use of Neurontin and the specific alleged injury, this issue of fact is not material and does not preclude summary judgment.

2. Plaintiff Fails To Prove Neurontin Was A Proximate Cause Of His Illness

Plaintiff's evidence is insufficient to create a genuine issue of material fact regarding whether Neurontin was a proximate cause of Plaintiff's illness. Plaintiff relies almost exclusively on the proffered testimony of Christopher A. Keeys in establishing causation. Therefore, in order to determine whether causation exists, the Court analyzes the Plaintiff's proffered expert testimony under the Federal Rules of Evidence as well as Defendant's *Daubert* challenge.[15]

a. Plaintiff's Expert Lacks The Specialized Knowledge Necessary To Aid The Jury In Determining Causation

Under *Rule 702*, expert testimony is admissible if it concerns (1) scientific, technical, or other specialized knowledge that (2) will aid the jury or other trier of fact to understand or resolve a fact at issue. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592 (1993); Fed. R. Evid. 702. In determining whether an expert's opinion is admissible, courts look to the qualifications of a proffered witness. *See Wehling v. Sandoz Pharms. Corp.*, 162 F.3d 1158, 1998 WL 546097 (4th Cir. Aug. 20, 1998) (unpublished). Under *Rule 702*, an expert's opinion must be grounded in some specialized skill, knowledge or experience in order to be relevant. *See Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 249 (4th Cir. 1999); Fed. R. Evid. 702. Therefore, there must be a fit between the expert's field of knowledge and the issues involved in the case. *See Bourne v. E.I. DuPont De*

[15] *Daubert* factors encompass both general and specific causation at issue in the present case.

Nemours & Co., 189 F. Supp. 2d 482, 495 (S.D.W. Va. 2002).

In the case at hand, Keeys' opinion is offered to establish a pharmacological link between Neurontin and pneumonia and/or pancreatitis. Keeys proposes to testify that gabapentin (Neurontin) was "probably the offending agent, and in the absence of medical etiologies, cause of acute pancreatitis and subsequent complications . . . including [Plaintiff's] respiratory illness." (Exhibit F at 2.) However, Keeys is not a doctor and has a degree in pharmacy – not pharmacology.[16] (Keeys Dep. at 8.) Without a degree in pharmacology, Keeys is not qualified to render a relevant or reliable pharmacological opinion regarding the effects of Neurontin. *Wehling*, 1998 WL 546097 (affirming the exclusion of expert with similar qualifications who sought to testify as to drug interactions where the expert was a retired pharmacist and toxicologist, rather than a pharmacologist or medical doctor).

In addition to a lack of professional training in pharmacology, Keeys readily admits that he has no specialized knowledge of, or experience with, pancreatitis or pneumonia. (Keeys Dep. at 108, 113.) Furthermore, Keeys never performed independent research on the pharmacologic design, efficacy or mechanism of Neurontin. (Keeys Dep. at 127, 129.) For these reasons, Keeys' opinion lacks the necessary background and expertise to qualify him as an expert witness on the issue of causation. Therefore, Keeys' opinion is inadmissible under Fed. R. Evid. 702.

b. Plaintiff's Expert's Opinion Is Not Reliable

In addition to lacking the requisite training and specialized knowledge to offer an opinion regarding causation, Keeys' reasoning and methodologies are unreliable based upon the factors set

[16] Pharmacology can be described as the study of the effect of drugs on living organisms, while pharmacy, on the other hand, can be described as the profession of reading prescription labels and dispersing drugs. *Devito v. SmithKline Beecham Corp.*, 2004 U.S. Dist. LEXIS 27374, at *26 N.3 (N.D.N.Y. 2004).

out in *Daubert*. In *Daubert*, the Supreme Court established a test to ensure that admitted expert testimony is both relevant and reliable.[17] *Daubert,* 509 U.S. at 590-92. In determining reliability, the following factors are considered: 1) whether the expert's reasoning or methodology has been or could be tested; 2) whether the expert's reasoning or methodology has been subject to peer review and publication; 3) the known potential rate of error; 4) and the level of acceptance of the expert's reasoning or methodology by the relevant professional community. *Id*. at 593-94.

Keeys' reasoning has not been adequately tested. Keeys relies on the following sources as the bases for his proffered expert opinion: product labels and data available from the FDA's adverse drug reaction reporting system (Medwatch), published biomedical literature related to drugs associated with acute pancreatitis, product inserts and additional data regarding unpublished reports of acute pancreatitis, and a lack of positive re-challenge with reinitiated medications in the Plaintiff. (Exhibit *F* at 2.)

Keeys' opinion is based primarily on eleven (11) abstract cases which deem gabapentin as the principle cause of injury. (*Id*.) However, Keeys himself concedes that case reports are not scientific proof of causation. (Keeys Dep. at 62.) In fact, under *Daubert*, many courts have recognized that adverse drug reaction case reports and other regulatory reports fail to test a causal hypothesis and therefore cannot support a causation opinion. *See Glastetter v. Novartis Pharm. Corp*., 252 F.3d 986, 989-90 (8th Cir. 2001)*; Hollander v. Sandoz Pharma. Corp*., 289 F.3d 1193, 1211 (10th Cir. 2002)*; Rider v. Sandoz Pharm. Corp*., 295 F.3d 1194, 1199 (11th Cir. 2002)*; Soldo v. Sandoz Pharm. Corp*., 244 F. Supp. 2d 434, 541 (W.D. Pa. 2003). Furthermore, courts have found

[17] The Rule 702 analysis overlaps to a large degree with the relevance inquiry described in *Daubert* and does not warrant a separate analysis.

case reports to be merely anecdotal accounts of observations in particular individuals which are not controlled tests, frequently lack analyses and often make little attempt to screen out alternative causes for a patient's condition. *Glastetter,* 252 F.3d at 989; *See Rider,* 295 F.3d at 1199; *Soldo,* 244 F. Supp. at 539 (citation omitted); *see also Cavallo v. Star Enter.*, 892 F. Supp. 756, 765-66 (E.D. Va. 1995).

Each of these suggested criticisms of adverse drug reaction case reports hold true here. The abstract cases relied upon by Keeys have not been tested or subject to peer review and lack a known potential rate of error. (Exhibit H.) The abstract reports simply describe reported drug cases without comparing them to the general population or a control group. Moreover, the reports fail to isolate potential alternative causes and neglect to investigate or explain the mechanism of causation. *See Lopez v. Wyeth-Ayerst Labs.*, 1996 WL 784566 (N.D. Cal.1996).

Keeys also relies heavily on PDR product inserts to support his findings on causation. According to Keeys' summary report, product label inserts show gabapentin (Neurontin) causes pancreatitis. (Exhibit F at 2.) In fact, Keeys reviewed the product inserts of Neurontin, Soma, Prozac, Zithromax, Vicadin and Elavil in the 1999 Physician Desk Reference ("PDR").[18] (*Id*.) Notably, Keeys reports that Neurontin (and possibly Soma) are the only drugs taken by Plaintiff that reported pancreatitis as a concern. (*Id.*) However, Keeys fails to include that the product label for Prozac, another medication Plaintiff was taking prior to hospitalization, also reported pancreatitis as a rarely observed adverse reaction.[19] (Keeys Dep. at 35-36.) Moreover, Keeys fails to include in

[18] All of the product inserts reviewed were medications taken by the Plaintiff prior to his hospitalization. (Exhibit G at 2.)

[19] Prozac was reported at the same frequency as Neurontin. Both product inserts stated that pancreatitis was reported as an adverse reaction observed rarely. (Keeys Dep. at 35-36.)

his summary report that a PDR package insert is *not* a final source of data and is *not* a pure science document. (*Id.*) Rather, the package insert is a regulatory document that is generated from science *and* a collaboration of the industry with the FDA. (*Id.*)

Likewise, Keeys' opinion regarding the temporal relationship between the Plaintiff taking Neurontin and becoming ill was never tested independently or by objective sources. (Keeys Dep. at 92.) Courts have found that a causation opinion based solely on a temporal relationship is not derived from the scientific method and is therefore insufficient to satisfy the *Daubert* standards. *Cavallo*, 892 F. Supp. at 773; *see also Roche v. Lincoln Prop. Co.,* 278 F. Supp. 2d 744, 764 (E.D. Va. 2003); *Rohrbough v. Wyeth Labs., Inc.*, 719 F. Supp. 470, 474 (N.D.W. Va. 1989). Furthermore, the temporal relationship in this case is tenuous at best due to the fact that Plaintiff's course of treatment included two separate regimens of Neurontin (for a total of 18 months of Neurontin use) before Plaintiff experienced any acute illness. (Keeys Dep. at 9, 15.)

Keeys also fails to provide alternative explanations for causation. Generally, courts exclude experts who fail to consider alternative causes or fail to offer an explanation for why the proffered alternative cause was not the sole cause. *See Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001); *See also Claar v. Burlington N.R.R.*, 29 F.3d 499 (9th Cir. 1994). In this case, Keeys never tested or addressed the possibility that other drugs, such as Duract, could be responsible for Plaintiff's injuries. (Keeys Dep. at 40.) In an attempt to rule out other potential medicines, Keeys explains in his report that the best way to determine a high probability of causation is to re-challenge a medication and observe whether the same effects occur. (*Id*. at 63.) Keeys then posits that the lack of a positive re-challenge with the Plaintiff's reinitiated medications (all but Neurontin), and the lack of published concerns of pancreatitis with the reinitiated medications strongly suggests the negligible

role these other medications, if any, may have had in causing Plaintiff's illness. (Exhibit H.) However, Keeys' theory is weakened by the Plaintiff's failure to re-challenge Neurontin, as well as the reasons explained herein with reference to the lack of significance of the PDR product label inserts. Furthermore, other potential causes such as heredity, obesity, trauma, pancreatic tumors and the long-term effects of the Plaintiff's heavy smoking were also never considered by Keeys in determining causation. (Keeys Dep. at 15, 145.) Therefore, Keeys' methodologies and conclusions are less reliable due to a general lack of testing.

Under *Daubert*, Keeys also fails to establish reliable scientific methods subject to peer review or publication. Keeys' opinion that Neurontin causes pancreatitis is not supported by medical or scientific literature. (Keeys Dep. at 29-30, 37.) Defendants' expert also noted that no studies or reports in medical literature established a link between Neurontin and pancreatitis or pneumonia. (Freiman Report at 3.) Further, Keeys' opinion regarding causation is not based on his own, preexisting, independent research.

In conclusion, without objective sources such as clinical studies or medical literature that are subject to factors set out in *Daubert* such as testing, peer review, and publication, Keeys' opinion fails to offer reliable methodologies that support the hypothesis that Neurontin is generally capable of causing Plaintiff's injuries. (Keeys Dep. at 37; Freiman Report at 3.) Furthermore, adverse case reports, along with other sources included in Keeys' report, neglect to prove a general level of acceptance among the relevant professional community. In fact, none of Keeys' sources, independently or collectively, establish a causal link between Neurontin and pneumonia or pancreatitis. (Keeys Dep. At 29-30, 37; Freiman Report at 3.) As a result, Keeys' expert opinion fails to satisfy the four factors of reliability set out in *Daubert*. Without relevant professional

qualifications or reliable conclusions, Keeys' expert opinion is insufficient to prove causation. *Daubert,* 509 U.S. at 590; *Tyger Constr. Co. v. Pensacola Constr. Co.*, 29 F.3d 137, 142 (4th Cir. 1994). As a result, Plaintiff's expert opinion regarding causation fails to create a genuine issue of material fact.

IV. ORDER

IT IS, THEREFORE, ORDERED that Defendants' Motions for Summary Judgment and to Exclude Testimony are both hereby **GRANTED.**

Signed: July 19, 2006

Richard L. Voorhees
United States District Judge